Army Regulation 40-660 DLAR 4155.26 NAVSUPINST 10110.8C AFR 161-42 MCO 10110.38C

**Medical Services** 

DoD Hazardous Food and Nonprescription Drug Recall System

Headquarters
Departments of the Army, the Defense
Logistics Agency, the Navy, the Air Force,
and the Marine Corps
Washington, DC
15 August 1986

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Not applicable.

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Effective 15 August 1996

#### **Medical Services**

### DoD Hazardous Food and Nonprescription Drug Recall System

BY ORDER OF THE DIRECTOR

JAMES J. SINGSANK
Colonel, USA
Staff Director, Administration

**History.** This publication has been reorganized to make it compatible with the Army electronic publishing database. No content has been changed.

**Summary.** This publication implements policy of the Office of the Under Secretary of Defense for Research and Engineering for the establishment of a hazardous food and nonprescription drug recall system. It has been coordinated with and concurred in by the DMSB and the Services.

Applicability. This publication is applicable to HQ DLA; DPSC; Defense Supply Centers (DSCs) with depot operations; Defense Depots (DDs); Army, Navy, Air Force, and Marine Corps communications facilities; and those activities of the Military Services including Reserve Forces (hereinafter referred to as the Services) involved in the contracting, inspection, administration, shipment, storage, distribution, issue, sale, preparation for feeding of food supplies, and use or sale of non-prescription drugs, nonprescription medical devices, and health and beauty aids.

**Proponent and exception authority.** The Proponent for this regulation is The Surgeon General (TSG).

Army management control process. Not applicable.

**Supplementation.** Supplementation is permitted by primary level field activities.

Suggested Improvements. Not applicable.

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#### I. Purpose and Scope.

To prescribe policy guidance and assign responsibilities within DoD to be followed when recalls of hazardous, tampered or suspected tampering of foods or nonprescription drugs, nonprescription medical devices, and health and beauty aids (hereinafter collectively called hazardous food and nonprescription drugs) are issued by the Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), U.S. Department of Commerce (USDC), Defense Personnel Support Center (DPSC), or other Government or non-Government agencies which concern foods or nonprescription drugs that are or may be expected to be in military accounts. As commissaries, exchanges, and other activities stock and distribute nonprescription drugs, nonprescription medical devices, and health and beauty aids, this recall system will be utilized to disseminate information on Class I and Class II recalls concerning these types of products in accordance with Defense Medical Standardization Board (DMSB) policy. Such notification is designed to supplement the customary recall information notices issued by the Military Medical Field Offices. This publication is applicable to HO DLA; DPSC; Defense Supply Centers (DSCs) with depot operations; Defense Depots (DDs); Army, Navy, Air Force, and Marine Corps communications facilities; and those activities of the Military Services including Reserve Forces (hereinafter referred to as the Services) involved in the contracting, inspection, administration, shipment, storage, distribution, issue, sale, preparation for feeding of food supplies, and use or sale of nonprescription drugs, nonprescription medical devices, and health and beauty aids. This publication implements policy of the Office of the Under Secretary of Defense for Research and Engineering for the establishment of a hazardous food and nonprescription drug recall system. It has been coordinated with and concurred in by the DMSB and the Services.

#### II. Policy.

HQ DLA, through its primary level field activity, DPSC, will act as the sole agent for DoD to coordinate all hazardous, tampered or suspected tampering of food and nonprescription drug recalls which may involve the Services. In this role, the agent will evaluate hazardous food and nonprescription drug recalls for DoD involvement, taking appropriate actions to protect the health of military personnel and their dependents, as well as the financial interests of DoD. DPSC will also advise the Military Medical Field Offices and DDs, as appropriate, of recall information on medical items. Retail activities, in addition, will be notified of Class I and Class II food and nonprescription drug recalls when there is definite knowledge that the items were procured for the exchanges and commissaries.

#### III. Definitions.

- a. <u>Authorized Medical/Food Inspection Personnel.</u>
- (1) Army Assigned veterinary service food inspection personnel.
- (2) Air Force Assigned environmental health service personnel.
- (3) Navy and Marine Corps Assigned medical inspection personnel in the absence of Army veterinary service support.
  - b. Class of Recall
- (1) Class I A Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- (2) Class II A Class II Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- c. <u>Communicators.</u> Individuals responsible for the receipt, transmission, and delivery of messages from one person or place to another.
- d. Food and/or Drug Accountable/Responsible Personnel. Individuals having accountability and/or responsibility for food and/or nonprescription drugs and their proper custody, care, and safekeeping while in the accounts of troop feeding facilities; while located at DDs, DSCs, and Supply Points; also those individuals with similar obligations at commissary stores, exchanges, clubs, and other appropriated or nonappropriated fund activities.
- e. <u>Food and Nonprescription Drug Recalls</u>. Announcements or alerts of emergency or priority situations involving the removal from the marketplace of hazardous foods or nonprescription drugs or suspect hazardous foods or nonprescription drugs, the consumption or use of which could produce consequences that would be immediate or long–range, life threatening, or hazardous to health.
- f. <u>Hazardous Foods or Nonprescription Drugs</u>. Foods or nonprescription drugs not free or suspected of not being free from disease or noxious elements, or conditions which would render them a health hazard or unfit for human consumption or use.
- g. <u>Military Medical Field Offices</u>. The U.S. Army Medical Materiel Agency (USAMMA), Frederick, MD 21701–50U1; the Naval Medical Materiel Support Command (NAVMEDMATSUPCOM), Philadelphia, PA 19145; and the Air Force Medical Logistics Office (AFMLO), Frederick, MD 21701–5001.
- h. <u>Nonprescription Drugs</u>. Over-the-counter drugs, health and beauty aids, and nonprescription medical devices that do not require a physician's prescription.
  - i. Tampering. Deliberate introduction or substitution of an adulterant, unwholesome material, or toxic substance to

or the alteration of a food or nonprescription drug or health and beauty aid or its packaging or labeling, the consumption or use of which may result in death or serious bodily harm.

#### IV. Significant Changes.

This publication has been updated to include tampering of food and nonprescription drugs, and current terminology.

#### V. Responsibilities

#### a. HQ DLA

- (1) The Executive Director, Quality Assurance, DLA (DLA-Q) will provide policy for and exercise staff supervision of the recall of DLA-managed food and nonprescription drug supplies.
- (2) The Chief, Depot Operations Division (DLA–OW), and the Chief, Supply Management Division (DLA–OS), Directorate of Supply Operations (DLA–O), will assure that the supply aspects of this regulation pertaining to the recall of OLA–managed items are administered efficiently and effectively.

#### b. Field Activities

- (1) The Commander, DPSC, will:
- (a) Be the sole point of contact with FDA, USDA, USDC, and other sources for all matters pertaining to recalls in furtherance of the policy stated in paragraph II above.
  - (b) Determine if any DLAmanaged stocks are involved by the recall.
  - (c) Determine location of involved food/nonprescription drug items managed by DLA.
- (d) Determine whether or not the hazardous item may be in the accounts of food/nonprescription drug accountable/responsible personnel.
- (e) Evaluate, in conjunction with responsible Federal agencies, reports of hazardous foods or nonprescription drugs or suspected hazardous food or nonprescription drug items received from food or nonprescription drug accountable/ responsible personnel, authorized military inspection personnel, medical personnel, or other sources; determine whether or not a hazardous food and nonprescription drug recall message should be dispatched to all users; and coordinate with FDA to determine if a military recall should be expanded to include the civilian community.
- (f) Prepare initial message for transmission by Automatic Digital Network (AUTODIN) which will be routed direct to user installations and activities worldwide, or only to specific location(s) stocking the item when this is known. As a minimum, these messages will contain the following:
- 1. The Defense Communications Agency (DCA) approved collective address designator code All Food/Drug Activities (ALFOODACT).
- 2. The applicable message serial number as taken from a sequence that begins and ends within a calendar year; e.g., the first message during CY 1984 would be numbered 1–84. The first message of the calendar year will summarize the previous calendar year ALFOODACT message activity and list open/unresolved recalls.
  - 3. Specific description of hazardous food or nonprescription drug and National Stock Number (NSN), if applicable.
  - 4. Brand name, if applicable.
  - 5. Name and address of processor/manufacturer, and country of origin if an imported item.
  - 6. Contract number, if applicable.
  - 7. Date of pack, container code or product code.
- 8. An advisory statement to users to place the hazardous food/nonprescription drug immediately in a "hold status" which will suspend its sale, issue, and use. If appropriate, advise Base/Post Public Affairs Office to notify general population of the installation to return the suspected hazardous food/nonprescription drug items to place of purchase.
  - 9. Final disposition instructions if known at this time; e.g., return product to recalling firm through local distributor.
  - (g) Assign priority precedence to ALFOODACT messages.
- (h) As necessary, prepare interim messages to users to advise of the progress of recall actions or status of the hazardous items involved.
  - (i) Advise users by message by final disposition of the recalled item.
- (j) Maintain a summary log of hazardous food/nonprescription drug recalls that as a minimum will include the following:
  - 1. Message number/ALFUODACT number.
  - 2. Item identification.
  - 3. Contract number, if applicable.
- (k) Prepare and transmit ALFOODACT test messages whenever a 90-day period of time has elapsed during which no recall has caused use of the system.
  - (2) Technical and Quality Assurance Division, Subsistence (DPSC-ST) will:
  - (a) Act as DPSC focal point for all recalls.
  - (b) Determine the necessity of issuing recalls. Obtain advice from DPSC-AT on nonprescription drug matters.
  - (c) Prepare recall messages. Coordinate with DPSC-AT in preparing recall messages for nonprescription drugs.

- (3) <u>Technical Operations Division</u>, <u>Medical (DPSC-AT)</u> will provide assistance and advice to <u>DPSC-ST</u> in determining necessity for issuing recalls and in preparation of messages involving nonprescription drug items.
  - c. Communicators will assure:
- (1) That ALFOODACT messages are processed in a manner appropriate to the "priority" communications precedence assigned.
- (2) Delivery of ALFOODACT messages to food or nonprescription drug account-able/responsible personnel of DDs, DSCs, supply points, commissary stores, food service offices, exchanges, clubs, open messes, authorized military inspection personnel, and veterinary/medical personnel.
- (3) Maintain a file of ALFOODACT messages by message serial number for a minimum of 1 year and provide a copy of messages to supported activities on request.
  - d. Food and/or Drug Accountable/Responsible Personnel will:
- (1) Upon notification, immediately act to identify stocks of hazardous food or nonprescription drugs that may be on hand, segregate those present, and secure the items in a hold status to preclude their immediate further issue, sale, and use. Responsible depot/supply point/nonappropriated fund activity personnel will notify the end users of hazardous food or nonprescription drug items in those instances when issue has been made prior to receipt of a DPSC message that has been directed only to that specific depot/supply point. Authorized food inspection or medical personnel may be requested to assist in all of these matters involving food recalls. In cases of nonprescription drug recalls, advice may be obtained from the responsible medical activity.
  - (2) As appropriate, notify parent commands of the amounts of hazardous items on hand.
- (3) Retain hazardous food or nonprescription drug items in a hold status until final disposition instructions have been received from DPSC.
- (4) Notify the Commander, DPSC, ATTN: DPSC–ST whenever hazardous foods or nonprescription drugs have been identified through local determination as being on hand in a local supply account. An information copy of such notification will be forwarded to the department headquarters of the Service, which originates the notification, and will be noted to the attention of medical and food service staff at department level.
- (5) In the event any DoD activity finds a condition of food that may require a hazardous recall, the local authorized food inspection or medical personnel will be contacted. In addition, all food and nonprescription drugs which are found that may require a hazardous recall will be reported to DPSC–ST via priority message which is to contain, as a minimum, the following:
  - (a) Specific description of hazardous item, and NSN, if applicable.
  - (b) Brand name, if applicable.
  - (c) Name and address of manufacturer/processor.
  - (d) Contract number, if applicable.
  - (e) Lot numbers (from case) or package/can codes.
  - (f) Activity that supplies material (Depot/Supply Center, DoD).
  - (g) Date material received at using activity.
  - (h) Amount received and amount in stock.
  - (i) Description of hazardous condition.
- (j) Symptoms of illness or death attributed to or suspected to be caused by the item, number of persons affected; and contact point for medical authority cognizant of the incident.
  - (k) Laboratories to which samples have been submitted for test/analysis, date shipped, and mode of shipment.
  - (1) Laboratory test/analysis results when available.
- (m) Where necessary, send samples to nearest laboratory with a request to furnish DPSC-ST with one copy of results on a priority basis.
- (6) In addition to the above procedure for reporting a suspected hazardous nonprescription drug item, report and process medical material complaints in accordance with the appropriate Service regulations (DLAR 4155.28: BUMEDINST 6710.63. AR 40–61; AFM 67–1, Vol V, Chap 19).
- (7) In addition to the above procedures for reporting a suspected hazardous food item, report and process subsistence material complaints in accordance with the appropriate Service regulations (DLAR 4155.3/AH 3/AR 30–12/NAVSUPINST 4355.2/ AFR 74–5/MCO 10110.21).
- (8) Retain copies of ALFOODACT messages for a minimum period of 1 year or until final disposition, whichever is later.
  - (9) Conduct inspections and submit samples to laboratories for testing as required.

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